

REMARKS

Claims 37 - 62 are in the application.

The claims have been amended to more particularly point out and distinctly claim applicant's invention. Composition claims 1-36 have been cancelled without prejudice for later presentation in a continuing application in favor of new process claims 37-62 of comparable scope. The new claims are fully supported by the application as filed and present no new matter.

Claims 1, 7-9, 17 and 32 stand objected to on formal grounds. These objections are respectfully traversed and reconsideration and withdrawal of the objection are respectfully requested in view of the present amendments.

In particular, the Examiner notes that with respect to claim 1, in line 3 the term "extemporaneously" should be changed to "instantly." The Examiner further notes that line 5 refers to "the medium", but antecedent basis is lacking, that in line 7 has the term "decomposition" should be changed to "disintegrated" and that line 9 refers to "it", but antecedent basis is lacking. Applicant has cancelled claim 1 but has refrained from using the term "extemporaneously" in the new process claims.

With respect to claims 7-9, the Examiner notes that the terminology "alkaline or alkaline-earth" apparently should be "alkali or alkaline-earth." Claims 7-9 have been cancelled, and the Applicant has not employed the terminology in the new process claims.

With regard to claim 17, the Examiner states that the potato, corn, etc. starches have undergone physical transformations to become starches. Claim 17 has been cancelled.

With regard to claim 32, the Examiner notes that the fourth from the last line has "at at", which apparently should read "to at." Claim 32 has been cancelled.

Claim 25 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is respectfully traversed as applicable to the amended claims, and reconsideration and withdrawal of the rejection are respectfully requested.

The Examiner states that claim 25 refers to alcohol content but it is unclear whether the alcohol is the hydroalcohol of claim 23 or the C₁₋₄ alcohols of claim 24. The Examiner helpfully points out that it may have been intended for claim 25 to depend from claim 24, referencing the specification at page 14, last paragraph. Claim 25 has been cancelled and care has been taken to try to avoid a comparable indefiniteness in the new process claims.

Claims 1-36 stand provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-40 of copending Application No. 10/511,260 ("the '260 application"). Applicant respectfully traverses this rejection and requests reconsideration and withdrawal of this provisional rejection.

The '260 application relates to sustained release from soft capsules, which depends upon the liquid content encapsulated in such soft capsules. The present application relates to the composition of the capsule shell, not the content *per se*. Thus, the presently claimed subject matter would not be obvious to one of ordinary skill in the art over the disclosure of the '260 application.

Nevertheless, should the cited copending application mature into an issued patent upon which the Examiner may issue a non-provisional rejection, or should the Examiner find otherwise patentable subject matter in the present case, Applicant plans to consider the preparation and filing of a suitable terminal disclaimer in the present application.

Claims 1-36 stand rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over U.S. Patent 6,331,205 ("Paris"). This rejection is respectfully traversed, and reconsideration and withdrawal of the rejection are respectfully requested as applicable to the amended claims.

The Examiner states that the present claims substantially overlap the teachings of Paris. The Examiner provides a helpful chart detailing alleged correspondences between the limitations of Applicant's composition of matter claims and the disclosure of Paris.

However, Paris does not identically disclose the presently claimed invention.

"A claim is anticipated only if each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference."

Verdegaal Bros. v Union Oil of California, 814 F.2d 628, 631 *Fed. Cir. 1987), cert. denied, 484 U.S. 827 (1987). The absence of an element of a claim from a prior art reference negates anticipation of that claim by that reference. Kloster Speedsteel AB v. Crucible, Inc., 793 F.2d 1565, 230 USPQ 81, on rehearing, 231 USPQ 160 (Fed. Cir. 1986), cert. denied, 479 U.S. 1034 (1987).

In a process for making soft capsules, a gelling agent is needed to form films from the mass of capsule-forming material when cooling the mass to around 12 °C. These films are then stretched and sealed under hot conditions, the films having, as their purpose, encapsulation of liquids under pressure. Paris discloses a process for making soft capsules using a gelling agent other than gelatin. The preferred gelling agent disclosed by Paris is *iota* carrageenan.

Before the present invention, nobody had succeeded to make soft capsules using a non gelling ingredient. In most of the cases, thickening agents are still mixed with a gelling agent such as gelatin, *iota* carrageenan, agar- agar, etc. In the presently claimed

invention, soft capsules are obtained by using thickening agents without the need to employ gelling agents such as gelatin. In one aspect of the presently claimed invention, films are obtained using thickening agents due to the fact that some thickening agents react strongly with selected ionic complexing agents, and the film sets instantly upon contact. In another aspect, other thickening agents react the same way with selected alcohols.

It should be noted that even if lambda carrageenan belongs to the same family as iota carrageenan, these two kinds of carrageenan do not have the same properties. Iota carrageenan is a gelling agent giving an elastic gel after cooling from a hot solution. However, lambda carrageenan is a thickening agent. Even after a hot solution of lambda carrageenan is cooled, no gel, like gelatin, is obtained. However, a solution of lambda carrageenan sets instantly in contact with a solution of calcium chloride, for example, giving a film like a gelatin film. Therefore, even if the ingredients arguably come from the same family, the process to obtain films for making soft capsules is simply not the same.

Paris discloses a process for making a film for manufacturing soft gelled capsules. A hydrocolloidal solution prepared by dissolving a suitable carrageenan in a solution buffer, and optionally dispersing an opaquing agent (col. 5, lines 31-43). The carrageenan solution is then simply "transferred towards the machines for manufacturing gelled capsules or soft capsules where the storing temperature is maintained between 80°C. and 90° C." (col. 5, lines 44-47). Presumably, the machines cool the carrageenan solution to gel the carrageenan and to "produce a more or less breakable film" (col. 1, lines 57-60).

Thus, while Paris arguably discloses the first step of the process presently claimed in applicant's sole independent claim 37, "dissolving at least one thickening

agent in an aqueous or hydroalcoholic dissolution medium to form a viscous encapsulating mass," Paris does not disclose any of steps (b), (c) or (d):

- (b) forming an ungelled film from the encapsulating mass;
- (c) providing a complexing solution comprising a film complexing agent to gelatinize the ungelled film; and
- (d) contacting the ungelled film with the complexing solution to instantly gel the ungelled film.

Consequently, because Paris does not disclose expressly or inherently, any of these three process steps, Paris cannot anticipate the presently claimed invention, and reconsideration and withdrawal of this rejection are respectfully requested for this reason.

Further, there is nothing in Paris which would teach or suggest the presently claimed invention to one of ordinary skill in the art at the time the invention was made.

A claimed invention is not patentable if its subject matter would have been obvious to a person of ordinary skill in the art. 35 U.S.C. § 103(a); *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1734 (2007). Facts which are relevant to a determination of obviousness include (1) the scope and content of the prior, (2) any differences between the claimed invention and the prior art, (3) the level of ordinary skill in the art and (4) relevant objective evidence of nonobviousness. *KSR Int'l Co.*, 127 S. Ct. at 1734. "A prima facie case of obviousness is established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art." *In re Bell*, 991 F.2d 781, 783 (Fed. Cir. 1993), *quoting In re Rinehart*, 531 F.2d 1048, 1051 (CCPA 1976). Further, [i]f an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious." *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1696 (Fed. Cir. 1988).

Paris simply discloses the use of novel materials, carrageenans, and preferably iota carrageenan, to provide gelatin-free soft capsules using a conventional process. The carrageenans are simply dissolved in a suitable medium, and then poured to form a film, which is subsequently dried (col. 4, lines 8-14). There is nothing in Paris which would teach, suggest or motivate one of ordinary skill in the art to (1) select a thickener which would react instantly with a complexing solution to form a gelled film, (2) provide a complexing solution; (3) form a film from a mass containing the thickener, or (4) contact the ungelled film with the contacting solution to instantly gel the ungelled film. Since independent claim 37 is unobvious over Paris, all the dependent claims must likewise be unobvious. Consequently, the Paris does not make out a *prima face* case of obviousness with respect to the presently claimed process invention, and reconsideration and withdrawal of the rejection entered under 35 USC 103(a) over Paris are respectfully requested for this reason.

Claims 1-36 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Paris in view of WO 01/007507 ("Scott"). This rejection is also respectfully traversed, and reconsideration and withdrawal of the rejection are respectfully requested as applicable to the amended claims.

The Examiner states that with respect to claim 2, Paris does not specifically teach the recited thickening agents other than the carrageenans, but Scott teaches those other thickening agents (citing p. 9, line 21, through p. 10, line 23) as well as the use of viscous aqueous liquids for making soft capsules (citing the Abstract). The Examiner concludes that in view of the record as a whole, therefore, it would have been obvious to substitute the carrageenan taught by Paris with the other thickening agents taught by Scott because both references teach viscous aqueous compositions for making soft capsules and Scott further teaches that other thickening agents would work

as well, citing *KSR Intern. Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1739 (2007), for the proposition that "[t]he combination of familiar [components] according to known methods is likely to be obvious when it does no more than yield predictable results."

However, Scott discloses a process for making hard capsules in a conventional dip molding process (page 6, lines 27-32). A setting agent or "system" is employed to gel a pullulan solution (page 6, lines 6-14). Pullulan hydrocolloids are mixed with a small amount of setting agent to obtain a gelled pullulan mass. The setting system gets the solution to set on the dipped pins in the capsule forming machine, thus assuring a uniform thickness.

In contrast, the presently claimed invention innovation does not employ a blend of a thickening agent and a gelling agent like those of Scott to form an ungelled film. At most, the present invention employs blends of thickening agents. Scott employs kappa carrageenan, which is a gelling agent known to give brittle gels. Likewise, Scott discloses an aqueous viscous composition for hard capsules. The compositions are necessarily totally different from those appropriate for soft capsules because the manufacturing processes. Simply making a gelled mass is not enough to produce soft capsules. Other parameters must be taken into account for manufacturing soft capsules, such as the thermo-reversibility of the mass, the elasticity of the films formed from the mass, et al., none of which are considered by Scott.

Thus, Scott adds nothing to Paris to teach, suggest or motivate one of ordinary skill in the art to provide a separate complexing solution, to form an ungelled film from a viscous encapsulating mass, or to contact the ungelled film with the complexing solution to instantly gel the ungelled film. Consequently, the combination of Scott and Paris does not establish a *prima facie* case of obviousness with respect to the presently claimed

invention. Reconsideration and withdrawal of the rejection, as applicable to applicant's present claims, are respectfully requested for this reason.

Reconsideration and an early notice of allowance are earnestly solicited.